UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OKLAHOMA

BRIAN C. HOWARD, M.D., and SUZANNE HOWARD,	)	
Plaintiffs,	)	
v.	)	**Case No. 02-CV-0564-CVE-FHM**
ZIMMER, INC.,	)	
Defendant.	)	

OPINION AND ORDER

Now before the Court is Defendant's Motion to Exclude the Chemir Report and the Testimony of Drs. Giandinoto, Hetzel, and Robertson (Dkt. # 196). Defendant seeks to exclude testing performed by Chemir Analytical Services (Chemir), the testimony of Dr. Giandinoto and Dr. Hetzel, and some of the testimony of Dr. Robertson. Plaintiffs have responded (Dkt. # 211) and argue that the report and testimony are reliable and relevant.

I.

Plaintiffs' complaint was filed on July 16, 2002, in the Northern District of Oklahoma. Dkt. # 1. In it, they allege that defendants[1] were manufacturers of a prosthesis known as the Sulzer Natural Knee II (NK-II) Tibial Baseplate, which was implanted in Brian Howard during a knee replacement surgery on or about June 13, 2000. Id. at 5-7. Plaintiffs allege that the tibial baseplate implanted in Brian Howard had residue on it that should have been removed during the manufacturing process. Id. at 2. They claim that the residue "prevented the tibial baseplates from

[1] The Court employs the term "defendants" based on the allegations in plaintiffs' complaint, but acknowledges that there is now only one party defendant.

bonding with [Brian] Howard's bone and triggered a painful inflammatory response, including extensive inflammation, membrane formation, and bone loss." Id. They further allege that the residue was present because defendants "made changes in the manufacturing process of [the] tibial baseplates to a process that included, but was not limited to, machining them after the porous coating was applied." Id. at 2-3. Brian Howard underwent surgery to replace the implant. Id. at 7. Plaintiffs' claims are based on those flaws in the manufacturing process that allegedly caused Brian Howard's knee implant to fail. Id. at 2-5, 10-19.[2]

At the time of plaintiffs' complaint, a number of similar complaints based on the defendants' manufacturing process were being filed. As a result, the Judicial Panel on Multidistrict Litigation transferred all federal cases based on the failure of the NK-II to the Northern District of Ohio for multi-district litigation pre-trial proceedings. Dkt. # 134, at 2. After identifying which implants had been manufactured with the new process, defendants entered into a settlement agreement with patients who had received them. Id. Plaintiffs' case was not included in the settlement because Brian Howard's device was not in a designated "affected lot." Id. However, plaintiffs allege that Brian Howard's device was similarly affected by flaws in the manufacturing process. In December 2010, the Judicial Panel on Multidistrict Litigation suggested that the case be remanded to the Northern District of Oklahoma because the class-action lawsuit against defendants had long been settled, and there would therefore be no continued efficiencies to deciding plaintiffs' claims in the Northern District of Ohio. Dkt. # 143, at 2, 4.

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[2] Following a partially successful defense motion for summary judgment, plaintiffs' only remaining claim is plaintiffs' negligence per se claim. In re Sulzer Hip Prosthesis and Knee Prosthesis Liab. Litig., 455 F. Supp. 2d 709, 722 (N.D. Ohio 2006).

II.

In Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), the Supreme Court held that district courts must initially assess the admissibility of "scientific" expert testimony under Fed. R. Evid. 702. The Supreme Court extended the gatekeeper role of federal district courts to all expert testimony in Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137 (1999). In Bitler v. A.O. Smith Corp., 400 F.3d 1227 (10th Cir. 2005), the Tenth Circuit discussed the role of district courts when considering a Daubert challenge to the admissibility of expert testimony. First, the court should make a preliminary finding that the expert is qualified to testify. Id. at 1232-33. Next, the proponent of expert testimony must establish that the expert used reliable methods to reach his conclusion and that the expert's opinion is based on a reliable factual basis. Id. at 1233. The Tenth Circuit cited four factors that district courts should apply to make a reliability determination:

> (1) whether a theory has been or can be tested or falsified; (2) whether the theory or technique has been subject to peer review and publication; (3) whether there are known or potential rates of error with regard to specific techniques; and (4) whether the theory or approach has "general acceptance."

Id. at 1233 (citing Daubert, 509 U.S. at 593-94). The Tenth Circuit was clear that "a trial court's focus generally should not be upon the precise conclusions reached by the expert, but on the methodology employed in reaching those conclusions." Id. In other cases, the Tenth Circuit has emphasized that any analytical gap in an expert's methodology can be a sufficient basis to exclude expert testimony under Daubert. Trucks Ins. Exchange v. MagneTek, Inc., 360 F.3d 1206, 1212-13 (10th Cir. 2004); Goebel v. Denver & Rio Grande W. R.R. Co., 346 F.3d 987, 992 (10th Cir. 2003). Under Daubert, "'any step that renders the analysis unreliable . . . renders the expert's testimony inadmissable. This is true whether the step completely changes a reliable methodology or merely

misapplies that methodology.'" Mitchell v. Gencorp Inc., 165 F.3d 778, 783 (10th Cir. 1999) (quoting In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 745 (3d Cir. 1994)).

III.

Chemir was contracted by plaintiffs to perform testing on the tibial baseplate of Brian Howard's NK-II. Dkt. # 197-3, at 2. Chemir was sent Brian Howard's NK-II. Id. The NK-II contains three components: the tibial baseplate, a tibial insert, and a femoral component. Id. Chemir was instructed to analyze only the tibial baseplate. Id. Chemir prepared a report describing its analysis of the NK-II. Dkt. # 197-4.

Chemir's report was based on Gas Chromatography/Mass Spectrometry (GC/MS) analysis. Id. at 3. In order to analyze the implant, all parts of it were extracted with methylene chloride. Id. The methylene chloride extract was analyzed using direct injection GC/MS. Id. at 4. The analysis detected the presence of hydrocarbons and fatty acids. Id. A sample of mineral oil in methylene chloride was also analyzed for quality control purposes. Id. This analysis revealed the presence of hydrocarbons in the mineral oil. Id.

Dr. Giandinoto was the project leader for Chemir's analysis of Brian Howard's NK-II. Dkt. # 197-2, at 10. He is acting as an expert witness for the plaintiffs, as is a Dr. Hetzel. See Dkt. # 197-6; Dkt. # 197-8. Dr. Robertson is a treating physician of Brian Howard. Dkt. # 197-10, at 2. He is also acting as an expert witness for the plaintiffs. Id. Zimmer argues that the Chemir report, Dr. Giandinoto's opinions, Dr. Hetzel's opinions, and some of Dr. Robertson's opinions should be excluded pursuant to Daubert.

A. The Chemir Report

Zimmer argues that methodology of Chemir's analysis was so poorly applied as to render the conclusions of Chemir's report unreliable.[3] Dkt. # 197, at 8. Zimmer alleges four specific flaws in the methodology employed by Chemir: (1) failure to maintain a chain of custody, (2) failure to conduct an extraction of the implant's container;[4] (3) extracting all three parts of Brian Howard's implant and failing to do control extractions of each part separately; and (4) failure to test the actual oils used to manufacture Brian Howard's implant. Id. at 8-9. Plaintiffs argue that these challenges, to the extent they can be substantiated, go only to the weight afforded to the report and not its admissibility. Dkt. # 211, at 6-7.

Zimmer first argues that there are no evidentiary materials establishing a chain of custody for Brian Howard's knee implant for the period between its removal and its shipment to Chemir.[5] Dkt. # 197, at 9. Zimmer further argues that, absent a full chain of custody, there is no way to eliminate the possibility that the detected hydrocarbons did not originate from post-explant handling and contamination. Id. Plaintiffs imply that a full chain of custody exists (see Dkt. # 211, at 10); however, there are no evidentiary materials suggesting that a chain of custody was maintained prior to Chemir receiving the implant. See generally Dkt. # 197-2; Dkt. # 197-3; Dkt. # 197-4; Dkt. # 197-6; Dkt. # 197-9; Dkt. # 197-10.

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[3] Zimmer does not argue that the method applied by Chemir, GC/MS analysis, is itself unreliable, only that Chemir's execution of the methodology was flawed. Dkt. # 197, at 8.

[4] Zimmer states that the extraction was conducted in a plastic container. Dkt. # 197, at 8. However, the evidentiary materials establish only that the extraction may have been conducted in a plastic container. Dkt. # 197-2, at 23.

[5] Chemir began and maintained a chain of custody upon receiving the implant. Dkt. # 197-2, at 25; Dkt. # 197-6, at 4-5.

Zimmer also argues that Chemir's failure to conduct a sample extraction of the implant's container renders the report's conclusions unreliable. Dkt. # 197, at 9-10. The implant was either extracted in its original container or placed into another container and extracted in that new container. Dkt. # 197-2, at 23; Dkt. # 197-6, at 5. The container in which the implant was extracted may have been made of plastic. Dkt. # 197-2, at 23.[6] A plastic container may contain low molecular weight hydrocarbons, and a plastic container may have been the source of the hydrocarbons detected by Chemir's GC/MS analysis. Dkt. # 197-1, at 5-6. Plaintiffs argue that, if the container needed to be tested, the analyst performing the test would have noted that the container needed to be tested and would have tested the container, because "the project analyst was a man of honesty and integrity, and a conscientious worker." Dkt. # 211, at 10. However, an expert's assurance is insufficient to prove that his methodology is reliable. Mitchell v. Gencorp Inc., 165 F.3d 778, 781 (10th Cir. 1999). Without a control sample extraction of the container, there is no way to determine if the container was the source of the hydrocarbons.

Zimmer argues that the Chemir report's conclusions are unreliable because Chemir extracted all three components of the implant. Dkt. # 197, at 10. Brian Howard's implant contained three components: the tibial baseplate, a tibial insert, and a femoral component. Dkt. # 197-3, at 2. Chemir was instructed to analyze only the tibial baseplate. Id. However, Chemir extracted and analyzed all three components together. Dkt. # 197-2, at 21; Dkt. # 197-4, at 3. The tibial insert was composed of ultra high molecular weight polyethylene. Dkt. # 197-1, at 5; see also Dkt. # 197-5, at 15. Ultra high molecular weight polyethylene contains low molecular weight aliphatic species.

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[6] Zimmer states that Dr. Giandinoto testified that the container "was likely a plastic container." Dkt. # 197, at 8. However, Dr. Giandinoto testified only that the container "may have been" a "plastic type of container." Dkt. # 197-2, at 23.

Dkt. # 197-1. The hydrocarbons listed in the Chemir Report as having been detected by Chemir's analysis (octacosane, hexacosane, and tetratriacontane)[7] are aliphatic species.[8] Dkt. # 197-4, at 4; see e.g., Xin Huang et al., Component Characteristics of Organic Matter in Hydrothermal Barnacle Shells from Southwest Indian Ridge, 31 Acta Oceanologica Sinica, no. 12, 2013 at 60, 63. There is disagreement as to whether the hydrocarbons in the tibial insert could have been detected by Chemir's GC/MS. Compare Dkt. # 197-1, at 5 (stating that the low molecular weight aliphatic species contained in ultra high molecular weight polyethylene "are extractable with common solvents and are detectable by GC-MS"), with Dkt. # 197-5, at 15 ("[T]he morphological structure of the polyethylene liner is such that nothing would be extracted out of it.").

Finally, Zimmer argues that the Chemir report was methodologically flawed and unreliable because it failed to test the actual oils used in the implant's manufacturing process and instead tested a mineral oil that was not used in the implant's manufacturing process. Dkt. # 197, at 11-12. Prior to testing, Chemir was informed as to which oils were used in the implant's manufacturing process. Dkt. # 197-3, at 2. Those oils are commercially available. Dkt. # 197-1, at 6. Those oils were not

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[7] A fourth hydrocarbon (hexadecane) was identified in Dr. Giandinoto's expert report as being present, but not in the Chemir report. See Dkt. # 197-6, at 5-6. Hexadecane is also an aliphatic species. See e.g., Xin Huang et al., Component Characteristics of Organic Matter in Hydrothermal Barnacle Shells from Southwest Indian Ridge, 31 Acta Oceanologica Sinica, no. 12, 2013 at 60, 63.

[8] It is not completely clear from the evidentiary materials that the hydrocarbons detected by Chemir are low molecular weight aliphatic species. See Dkt. # 197, at 5. However, it is strongly implied that they are. See Dkt. # 197, at 5-6 (first discussing the ability of low molecular weight aliphatic species to be extracted from ultra high molecular weight polyethylene then immediately stating that the three hydrocarbon components detected by Chemir were likely to have been extracted from the ultra high molecular weight polyethylene).

mineral oils. Id. at 4.[9] "It is common chromatography practice to run the actual components identified in the initial screening run to ensure that the database match is accurate." Id. at 6; see also id. at 6-7 ("[A]ccepted practice in chromatography . . . requires that multiple solutions of known concentration of the actual compounds in question (e.g. the manufacturing lubricants used by Sulzer) are run through the same GC-MS system as used on the unknown sample."). However, Chemir did not analyze any of the oils used in the manufacturing process. Dkt. # 197-2, at 26. Instead, it analyzed a mineral oil. Dkt. # 197-2, at 28; Dkt. # 197-4, at 4. Zimmer's evidentiary materials suggest that Chemir failed to follow standard GC/MS procedure by analyzing a mineral oil instead of the actual oils used in manufacturing the implant. Dkt. # 197-1, at 6-7. But cf. Dkt. # 197-6, at 4 (asserting that Chemir adheres to standardized procedures designed to ensure reliability)

Plaintiffs argue that mineral oils are a mix of hydrocarbons and that the hydrocarbons detected by Chemir would be present in any mineral oil. Dkt. # 211, at 11. However, this argument is predicated on the fact that the oils used in the manufacturing process were mineral oils. Because the evidentiary materials suggest that those oils were not mineral oils, see Dkt. # 197-1, at 4,[10] this argument is inapplicable.

"Under *Daubert* 'any step that renders the analysis unreliable . . . renders the expert's testimony inadmissable. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology.'" Mitchell v. Gencorp Inc., 165 F.3d 778, 783 (10th Cir.

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[9] Dr. Giandinoto believes that one or more of the oils used may have a mineral oil component, but he is unsure. Dkt. # 197-2, at 19; Dkt. # 211-5, at 42.

[10] It is possible that the oils used in the manufacturing process contain the specific aliphatic species identified in the Chemir report. See Dkt. # 197-1, at 4 (stating that the oils used in the manufacturing process contained unspecified aliphatic hydrocarbons). However, there is no evidentiary material suggesting that this is the case.

1999) (quoting In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 745 (3d Cir. 1994)). While plaintiffs argue that each individual error is insufficient to render the Chemir report unreliable,[11] it is clear that the combination of the four errors is sufficient. Because of these misapplications of an otherwise reliable methodology, it is unclear if the detected substances were introduced between the time NK-II was explanted and its arrival at Chemir, if the detected hydrocarbons were even present on the tibial baseplate (as opposed to being present on either the NK-II's container or the tibial insert), and if the detected hydrocarbons were even present in the specific oils used during the manufacturing process. Especially egregious is Chemir's failure to test only the tibial baseplate, despite clear instructions to do so. Chemir's report is so unreliable as to be inadmissable. Zimmer's motion should be granted to the extent it seeks to exclude the Chemir report.

B. Dr. Giandinoto's Opinions

Zimmer seeks to exclude the testimony of Dr. Giandinoto because his testimony is based on the Chemir report and because he is unqualified to testify as to regulatory compliance. Dkt. # 197, at 15.[12] As discussed supra, the Chemir report does not withstand Daubert scrutiny. Because the Chemir report is unreliable, the opinions based upon its data are also unreliable and should be

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[11] For example, plaintiffs argue that chain of custody issues generally go to the weight of the evidence and not its admissibility. Dkt. # 211, at 10; see e.g., United States v. McCluskey, 954 F. Supp. 2d 1224, 1264 (D.N.M. 2013) (applying United States v. Yeley-Davis, 632 F.3d 673 (10th Cir. 2011), to a Daubert inquiry).

[12] Although Zimmer casts aspersions at Dr. Giandinoto's current line of work, Zimmer is not disputing that Dr. Giandinoto is qualified to offer his opinions on matters related to organic chemistry. See Dkt. # 197, at 14 (stating that "Dr. Giandinoto owns a company that sells 'harmonic resonance' compact discs and claims that listening to the CDs will cure a litany of problems" and that Dr. Giandinoto's business "also sells equipment to magnetize water, which he claim is beneficial for crop germination."); Dkt. # 218, at 6 ("Zimmer did not challenge Dr. Giandinoto's education and prior work experience.").

excluded. See Student Mktg. Grp., Inc. v. Coll. P'ship, Inc., 247 Fed. App'x 90, 101 (10th Cir. 2007) (stating that reliability concerns can arise from an expert's data).[13]

Zimmer also seeks to exclude the opinions of Dr. Giandinoto dealing with regulatory compliance. Dr. Giandinoto admits that he is not an expert with respect to FDA regulatory requirements dealing with medical devices. Dkt. # 197-2, at 31; see also id. at 15 (attesting to knowledge of chemical regulatory requirements, but not to knowledge of medical device regulatory requirements). Because Dr. Giandinoto admits that he is not an expert in medical device regulatory requirements and because testimony on medical device regulatory requirements does not fall within the reasonable confines of organic chemistry, Dr. Giandinoto is not qualified to offer opinions on medical device regulatory requirements. See Ralston v. Smith & Nephew Richards, Inc., 275 F.3d 965, 969-70 (10th Cir. 2001).[14]

However, Dr. Giandinoto does provide some opinions that are neither based upon the Chemir report, nor concern regulatory compliance. See e.g., Dkt. # 197-6, at 11 (opining on the conditions under which mineral oil residue would be removed). Zimmer has not provided any arguments as to why these opinions should be excluded. See generally Dkt. # 197; Dkt. # 218. Therefore, those opinions should not be excluded. Zimmer's motion should be granted to the extent that it seeks the

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[13] This and other unpublished opinions are cited for their persuasive value. See 10th Cir. R. 32.1(A).

[14] Dr. Giandinoto does state that in reaching his opinions on medical device regulations he "researched on the Internet" and that, because of his knowledge of pharmaceutical regulations, he "get[s] the general idea of what needs to be done." Dkt. # 197-2, at 32. This is insufficient to render Dr. Giandinoto qualified to offer opinions in an area in which he is admittedly not an expert and which does not fall within the reasonable confines of organic chemistry.

exclusion of Dr. Giandinoto's opinions regarding regulatory compliance and the opinions of Dr. Giandinoto that are based upon the Chemir report. It should be denied in all other respects.

C. Dr. Hetzel's Opinions

Zimmer argues that Dr. Hetzel's opinions should be excluded because they are based upon the Chemir report, because they examine the meaning of the FDA's Good Manufacturing Practice (GMP) regulations, and because they are otherwise based upon nothing but Dr. Hetzel's ipse dixit. Dkt. # 197, at 16-19. As discussed supra, the Chemir report does not withstand Daubert scrutiny. Because the Chemir report is unreliable, the opinions drawn from its data are also unreliable and should be excluded. See Student Mktg. Grp., Inc. v. Coll. P'ship, Inc., 247 Fed. App'x 90, 101 (10th Cir. 2007) (stating that reliability concerns can arise from an expert's data). Additionally, Zimmer is correct that the law of the case is that Hetzel is "not competent to testify to legal conclusions about what the GMPs require." Dkt. # 133, at 8-9. Any opinions of Dr. Hetzel purporting to state what FDA GMPs require should be excluded.

Zimmer argues that Dr. Hetzel's opinions regarding stearic acid and polydimethyl silocone (PDMS) are supported by nothing more than his ipse dixit. Dkt. # 197, at 18-19. Dr. Hetzel states that the presence of stearic acid and PDMS is supported by the Chemir report. Dkt. # 197-5, at 13-

14.[15] Dr. Hetzel's statements on the presence of stearic acid and PDMS are either ipse dixit or based upon an unreliable report and both should be excluded.

Zimmer also argues that Dr. Hetzel's opinions regarding metallic particulates are supported by nothing more than his ipse dixit. Dkt. # 197, at 18-19. The Chemir report does not identify metal particulates as being present on Brian Howard's implant. See generally Dkt. # 197-4; see also Dkt. # 197-5, at 10. Dr. Hetzel did not examine Brian Howard's implant. Dkt. # 197-5, at 7. Dr. Hetzel admits that the only evidence that metal particulates were on Brian Howard's implant is that the implant was "grit blasted" with metal particulates during the manufacturing process and that the implant's premature loosening parallels the loosening of affected products. Id. at 10-11.[16] However, there are a number of possible causes of premature loosening of an implant. See Dkt. # 197-9, at 31. Without further evidence that Brian Howard's particular implant was contaminated with metal particulates, the factual basis for Dr. Hetzel's opinion regarding metallic particulates is so

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[15] Dr. Hetzel's opinion on stearic acid is actually supported by the Chemir report and is not merely his ipse dixit. Stearic acid is a fatty acid and is also known as octadecanoic acid. Webster's New Collegiate Dictionary 1130 (Henry Bosley Woolf et al. eds., 1981); F D Gunstone & B G Herslof, Lipid Glossary 2, at 150 (2000). The Chemir report states that fatty acids were detected. Dkt. # 197-4, at 4. Additionally, the Chemir report contains an analysis of octadecanoic acid. Id. at 33; see also id. at 36 (showing an analysis of "Octadecanoic acid, butyl ester"). However, because the Chemir report is unreliable, Dr. Hetzel's opinions regarding stearic acid should still be excluded. This Court is unable to find support for Dr. Hetzel's statement that the Chemir report identifies PDMS as being present on the implant.

[16] Dr. Hetzel also refers to research done on affected implants and implants other than the NK-II. Dkt. # 197-5, at 9-12, 20. However, this research fails to show that Brian Howard's particular implant contained metallic particulates on its surface.

questionable as to render his opinion unreliable.[17] See Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 149 (1999). Dr. Hetzel's opinions regarding metallic particulates should be excluded.

All of Dr. Hetzel's opinions appear to be based on the Chemir report, the requirements of FDA GMPs, or the presence of stearic acid, PDMS, or metallic particulates. See Dkt. # 197-8, at 5-6. Therefore, Zimmer's motion should be granted to the extent that it seeks the exclusion of Dr. Hetzel's opinions.

D. Dr. Robertson's Opinions

Zimmer also argues that one of Dr. Robertson's opinions is not based on scientific analysis and fails Daubert's "fit" requirement. Dkt. # 197, at 20. In his report, Dr. Robertson states that he had "only seen one other aseptic loosening similar to that of Dr. Howard's and that was related to a knee implant which was a subject of the Sulzer Recall proceedings," that the "course of events experienced by Dr. Howard was the same or substantially similar to that experienced by the patient who received an affected product," and that Dr. Robertson advised Brian Howard that "his operative findings were identical were identical or substantially similar to a patient who had received an affected implant from the Sulzer litigation." Dkt. # 197-10, at 6-7. These statements express Dr. Robertson's opinion that the experience of Brian Howard was the same as the experience of a patient who had an affected product. Zimmer has no objection to the remainder of Dr. Robertson's opinions. Dkt. # 197, at 20.

Plaintiffs argue that because the experiences of Brian Howard and the patient with the affected product were identical or substantially similar, Dr. Robertson's opinion withstands Daubert

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[17] Dr. Hetzel details a process by which it could be determined if metallic particles were present on Brian Howard's implant. Dkt. # 197-5, at 21. However, it appears that this test was never performed. Id.

scrutiny. Dkt. # 211, at 21. However, Dr. Robertson admits that, beyond the fact that both patients experienced aseptic loosening of their implants, the only significant similarity between the two was that both had implants that were removed more easily than Dr. Robertson had anticipated. Dkt. # 197-9, at 29-30.[18] There is no evidence that any further scientific inquiry was conducted to determine the extent of the similarities between Brian Howard's experiences and those of the other patient. See generally Dkt. # 197-9; Dkt. # 197-10. The sole basis for Dr. Robertson opinion appears to be that both Brian Howard and the other patient had aseptic loosening and that both patients' implants were easier to remove than anticipated. Plaintiffs have failed to establish that this comparison is reliable. Plaintiffs have not provided evidence that this comparison has been subject to peer review and publication, that there is an established rate of error for this comparison, or that this comparison has general acceptance. See Bitler v. A.O. Smith Corp., 400 F.3d 1227, 1233 (10th Cir. 2005). Dr. Robertson's methodology for reaching the conclusion that Brian Howard and his other patient's experiences were substantially identical is insufficiently rigorous, and, as a result, his opinion should be excluded. See Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137 (1999) ("[The objective of Daubert's gatekeeping requirement] is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.").

Plaintiffs cite Wheeler v. John Deere Co., 862 F.2d 1404 (10th Cir. 1988), and Four Corners Helicopters, Inc. v. Turbomeca, S.A., 979 F.2d 1434 (10th Cir. 1992), for the proposition that

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[18] One similarity between the two, which Dr. Robertson apparently did not believe to be significant, was that neither of the patients' implants were cemented. Dkt. # 197-9, at 18, 28. A number of other characteristics of the two patients' conditions were either dissimilar or unknown to Dr. Robertson. Id. at 28.

substantially similar accidents may be introduced as evidence. Both cases are inapposite. Notwithstanding the fact that Wheeler and Four Corners concern strict products liability actions and plaintiffs' sole remaining claim is for negligence per se, neither case concerns expert opinions subject to Daubert scrutiny. The question at issue in this motion is whether Dr. Robertson may provide an expert opinion that the situation of Brian Howard and that of his other patient were identical or substantially similar, not whether evidence relating to the other patient's implant is admissible. Consequently, the rule announced in Wheeler and Four Corners is inapplicable. Zimmer's motion to exclude Dr. Robertson's expert testimony on this issue should be granted.

IT IS THEREFORE ORDERED that Defendant's Motion to Exclude the Chemir Report and the Testimony of Drs. Giandinoto, Hetzel, and Robertson (Dkt. # 196) is **granted in part and denied in part**. It is granted as to the Chemir Report; Dr. Giandinoto's opinions on medical device regulatory requirements and the opinions of Dr. Giandinoto that are based upon the Chemir report; Dr. Hetzel's opinions; and Dr. Robertson's opinion that the experience of Brian Howard was the same as the experience of a patient who had an affected product. It is denied in all other respects.

IT IS FURTHER ORDERED that these rulings will govern consideration of the pending motion for summary judgment, as well as the admissibility of the subject evidence at trial.

DATED this 6th day of March, 2014.

Claire V Eagan

CLAIRE V. EAGAN
UNITED STATES DISTRICT JUDGE